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ORIGINAL

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

**LASANDRA MADDEN AND LEVELL
MADDEN, Individually, and on Behalf
of LABREA WILLIAMS, a minor child,**

Plaintiffs,

WYETH, d/b/a WYETH, INC., f/k/a \$
 AMERICAN HOME PRODUCTS \$
 CORPORATION; WYETH CONSUMER \$
 HEALTHCARE, AN UNINCORPORATED \$
 DIVISION OF WYETH, f/k/a WHITEHALL- \$
 ROBINS HEALTHCARE; & WHITEHALL \$
 LABORATORIES, INC. \$

Defendants.

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 79. **Sentiment**
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 81. **Passion**
 82. **Love**
 83. **Friendship**
 84. **Relationship**
 85. **Connection**
 86. **Link**
 87. **Bridge**
 88. **Path**
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 90. **Route**
 91. **Pathway**
 92. **Trail**
 93. **Track**
 94. **Footpath**
 95. **Highway**
 96. **Main Road**
 97. **Expressway**
 98. **Freeway**
 99. **Interstate**
 100. **Superhighway**

CIVIL ACTION No. 3:03-CV-0167-R

**U.S. DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
FILED**

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CLERK, U.S. DISTRICT COURT

By _____
Deputy

**PRETRIAL DISCOVERY ORDER ON PLAINTIFFS' MOTION AND
BRIEF TO COMPEL DISCOVERY FROM DEFENDANT WYETH**

On this the 21 day of November, 2003, came on to be heard and considered Plaintiffs' Motion and Brief to Compel Discovery from the Defendant Wyeth in this case, and this court, U.S. Magistrate ^{Judge} ~~Kaplan~~ sitting, having reviewed the pleadings and heard argument of counsel, and is of the opinion that plaintiffs' motion should be partially granted, **HEREBY ORDERS:**

Generic disputes:¹

- A) Whether Wyeth's GSSE, S3, WATSIN, and Sales information electronic databases should be identified and produced in their entirety, in electronic format.**
- D) Whether defendants are entitled to assert an objection/limitation on documents**

¹ These are the generic disputes referenced on pp. 7-8 of the Joint Status Report.

Pretrial Discovery Order on Plaintiffs' Motion and Brief to Compel Discovery from Defendant Wyeth

produced limited to those adverse events or injuries allegedly suffered by LaBrea Williams (scope of production).

Plaintiffs will be allowed supervised access by an expert of their choice to defendant's adverse event databases referenced in the motion to the extent they exist, e.g. GSSE, S3, and WATSIN, to determine what the cost will be to access and/or duplicate these databases and produce the information that plaintiffs want from them in readable, accessible, and printable electronic form. (Tr. of Hrg., 31) Alternatively, plaintiffs may take the deposition of Wyeth's Manager of Information Systems, or similar person, and may have their expert present at this deposition, to determine the cost of reproducing the information that plaintiffs want from defendant's databases in readable, accessible, and printable electronic form. The court will then decide whether to order the production of the electronic databases, and whether or not to assess the cost of such reproduction against the plaintiffs. (Tr. of Hrg., pp.31-34).

As to the Sales Information Database, Wyeth is ordered to describe generically the information on this database, so plaintiffs can make a determination whether or not they want to seek production of this database in electronic form.. (Tr of Hrg., p.47). If the description of this information is itself confidential, it is the court's opinion that the description shall be provided in conformity with the protective order agreed to by the parties. (Id. at 48).

Scope of production.

As to the scope of the production of the requests seeking NDA's, clinical trials data, and pre- and post-marketing ADE's and all underlying documents, as well as foreign ADE's and foreign advertising, the court orders that Wyeth produce all requested paper documents that manifest the symptomatology that plaintiff LaBrea Williams experienced (Tr. at 30 & 42); and

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all plaintiffs are required to do is show defendant some evidence of her symptoms, and any requested documents (NDA's, clinical trials documents, and/or pre- and post-marketing domestic and foreign ADE's) containing those symptoms are the documents that they are to receive. (Id. at 36). Plaintiffs are not required to have alleged such symptoms in the pleading. (Id. at 40). The symptoms that plaintiffs' medical records reference, and which will be the basis of this order, are attached as Att. 1 to this Order.

B) Whether Wyeth should produce worldwide/international documents.

First, the court notes that the defendant has agreed to give the plaintiffs all foreign labeling and foreign warnings, and so the only remaining issue is about foreign ADE's with all underlying documents and foreign advertising. (Tr. of Hrg., pp. 37, 38, & 42). Therefore, the court orders that Wyeth is to produce all foreign ADE's and advertising dealing with the symptomatology that plaintiff LaBrea Williams suffered, as ordered under "Scope of Production" above, and plaintiffs are not required to have alleged such symptoms in their pleading, but must show some evidence of them. Such symptoms are listed on Att. 1 to this order.

C) Lawsuits/notices of claims/labels pertaining to Adult Advil.

Defendant is ordered to produce all lawsuits, notices of claims, labeling, and warnings dealing with Adult Advil, again dealing with the symptomatology that plaintiff LaBrea Williams suffered, as ordered under "Scope of Production" above, and as noted above, the plaintiffs are not required to have alleged such symptoms in their pleadings, but must show some evidence of them. Such symptoms are likewise listed on Att. 1 to this order.

E) All manuscripts of any unpublished and published medical articles.

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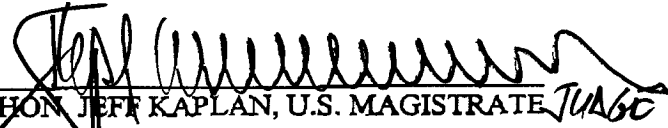
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Defendant is ordered to produce all unpublished manuscripts of the Ashraf article in its possession. (Tr. of Hrg., pp. 43-44)

Defendant Wyeth is ordered to fully comply with this Order within 30 days of the date of this Order.

Signed this 8th day of December, 2003.


HON. JEFF KAPLAN, U.S. MAGISTRATE JUDGE

APPROVED AS TO FORM:


JAMES C. BARBER, ATTY. FOR PLAINTIFFS


SCOTT FUQUA, ATTY. FOR DEFENDANT

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ATTACHMENT 1

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ATTACHMENT 1

**Summary of symptoms
for
Labrea Williams**

Symptom	Med DRA	Source	Page number
rash	skin & subcutaneous	Medical City	Page 2
fever	general	Medical City	Page 2
erythema multiforme	skin	Medical City	Page 3
drug hallucinosis	psychiatric	Medical City	Page 3
hyposmolality	renal	Medical City	Page 3
hypokpotassemia	renal	Medical City	Page 3
erythematous condition	skin	Medical City	Page 3
adverse effect/allergic reaction	injury & poisoning	Medical City	Page 3
hypocalcemia	musuloskeletal, connective & bone	Medical City	Page 3
major skin disorders	skin	Medical City	Page 3
blister	skin	Medical City	Page 29
erythematous papule	skin	Medical City	Page 29
itchiness (pruritis)	skin	Medical City	Page 29
blisters on lips	skin	Medical City	Page 29
emesis (vomiting)	skin	Medical City	Page 29
tachycardia	cardiac	Medical City	Page 29 & 83
hypotensive	renal	Medical City	Page 29
oral involvement (mucous membrane)	GI	Medical City	Page 29
sore throat	GI	Medical City	Page 30
conjunctivitis	eye	Medical City	Page 31
vesicles	skin	Medical City	Page 31
swollen lips	skin	Medical City	Page 31
bullous lesion	skin	Medical City	Page 31
erythematous pharynx	respiratory	Medical City	Page 31
maculopapular rash, lesions (all over body)	skin	Medical City	Page 31
mattering of eyes (eye disorder)	eye	Medical City	Page 33
injection of eye	eye	Medical City	Page 33
itching, dry eyes	eye	Medical City	Page 33
somnolent (malaise & fatigue)	general	Medical City	Page 33

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discomfort	general	Medical City	Page 33
vesicular rash	skin	Medical City	Page 33
eyelid lesions	eye	Medical City	Page 33
agitation	psychiatric	Medical City	Page 33
stevens johnson syndrome	skin	Medical City	Page 33
desquamation (all over body)	skin	Medical City	Page 25 & 27
vesicular bullous lesions	skin	Medical City	Page 25
electrolyte abnormalities	renal	Medical City	Page 25
enantherm	skin	Medical City	Page 25
cutaneous pain	skin	Medical City	Page 25
crusted eyes (eye disorder, lacrimation disorder, vision disorder)	eye	Medical City	Page 25
mucositis		Medical City	Page 25
eruption		Medical City	Page 28
aphthous ulcers (stomatitis)	GI	Medical City	Page 28
encephalitis	neuro	Medical City	Page 28
shivering (chills)	general	Medical City	Page 35
bullae	skin	Medical City	Page 35
macules	skin	Medical City	Page 35
erythematous	skin	Medical City	Page 35
edematous (face, arms, chest, all extremities, hands, feet, back, abdomen)	skin	Medical City	Page 35
crusty lips	skin	Medical City	Page 35
crusty neck	skin	Medical City	Page 35
vulvar involvement urogenital system, urogenital disorder, female genital disorder,	renal & urological	Medical City	Page 35
labia involvement	renal & urological	Medical City	Page 35
oral involvement (salivation disorder, miscellaneous buccal disorder)	GI	Medical City	Page 35
abdominal discomfort	GI	Medical City	Page 37
pustule	skin	Medical City	Page 37
mouth vesicle	GI	Medical City	Page 37
vesicular eruption	skin	Medical City	Page 37
hemorrhagic bullae	skin	Medical City	Page 37

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friable oral mucosa	GI	Medical City	Page 37
mouth lesions	GI	Medical City	Page 38
finger lesions	skin	Medical City	Page 38
abnormal skin		Medical City	Page 41
dry and cracked lips	skin	Medical City	Page 41
toxic epidermal necrolysis (TEN)	skin	Medical City	Page 41
encephalopathy	neuro	Medical City	Page 42
spit up blood (hemoptysis)	respiratory	Medical City	Page 48
soft tissue swelling	renal	Medical City	Page 48
ulcerative coating (mouth, lips, eyes)	GI	Medical City	Page 48
mouth sore			
dermatitis	skin	Medical City	Page 60
necrosis		Medical City	Page 60
subepidermal vesicle	skin	Medical City	Page 60
lab abnormality hepatotoxicity	hepato-biliary	Medical City	Page 66
lab abnormality - protein	disorders of metabolism	Medical City	Page 66
lab abnormality - glucose	disorders of metabolism	Medical City	Page 66
lab abnormality - liver enzymes	hepato-biliary	Medical City	Page 66
lab abnormality - calcium	musculoskeletal	Medical City	Page 66
lab abnormality - potassium	renal	Medical City	Page 66
lab abnormality - sodium	renal	Medical City	Page 66
lab abnormality - chloride	renal	Medical City	Page 66
lab abnormality - CO2	renal	Medical City	Page 66
lab abnormality - albumin	metabolism	Medical City	Page 66
lab abnormalities	general	Medical City	Page 66
facial edema	skin	Medical City	Page 66
urogenital redness	urological	Medical City	Page 84
urogenital pustules	urological	Medical City	Page 84
generalized weakness (musculoskeletal)	musculoskeletal	Medical City	Page 84
head, ears, nose, mouth throat pustules	respiratory & disorders of ear	Medical City	Page 84
oral lesions	GI	Medical City	Page 84
restless	psychiatric	Medical City	Page 90

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sore body	general	Medical City	Page 90
burning with urination	urological	Medical City	Page 90
reduced po intake	metabolism & nutrition	Medical City	Page 90
photophobia	neuro	Medical City	Page 92
mouth pain	GI	Medical City	Page 92
sloughing skin	skin	Medical City	Page 92
altered mental status	psychiatric	Medical City	Page 92
torn skin	skin	Medical City	Page 93
hanging pustules from neck	skin	Medical City	Page 93
open lesions or sores	skin	Medical City	Page 93
yellow drainage from lesions	skin	Medical City	Page 93
diarrhea	GI	Medical City	Page 95
incontinent	urological	Medical City	Page 96
gynecological redness, pustules, lesions	urological	Medical City	Page 96
generalized edema	renal	Medical City	Page 96
impaired vision	eye	Medical City	Page 96
blood in urine	renal	Medical City	Page 102
lethargy/drowsiness	neuro	Medical City	Page 105
nausea	GI	Medical City	Page 105
skin peeling	skin	Medical City	Page 105
red dots	skin	Medical City	Page 105
sore throat	GI or respiratory	Medical City	Page 112
headache	neuro	Medical City	Page 115
puffy eyes	eyes	Medical City	Page 115
swollen tongue	GI	Medical City	Page 113
hot flashes	general	Medical City	Page 119
mouth pain	GI	Medical City	Page 119
lip pain		Medical City	Page 119
general aches		Medical City	Page 119
pharyngeal erythema	respiratory	Medical City	Page 123
bullous impetigo	skin	Medical City	Page 123
extremities-erythematous	skin	Medical City	Page 123
dehydration	renal	Medical City	Page 123
respiratory distress, dyspnea, SOB,	respiratory	Parkland	Page 1
uti	urological	Parkland	Page 1
uri	respiratory	Parkland	Page 1
anemia	disorder of blood	Parkland	Page 1
distended abdomen	GI	Parkland	Page 130
vaginal ulcers	urological	Parkland	Page 131

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purpuric lesions	skin	Parkland	Page 131
malnourishment	metabolism & nutrition	Parkland	Page 137
edematous lips	skin	Parkland	Page 150
perineal and rectal disorder	GI	Parkland	Page 219
kidney toxicity (laboratory abnormalities -BUN, CR)	renal	Parkland	Page 13